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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/017,798

12/12/2001

Valentin Kramer

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09/20/2007

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INTELLECTUAL PROPERTY DEPARTMENT
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EXAMINER

CHANG, VICTOR S

ART UNIT

PAPER NUMBER

1771

MAIL DATE

DELIVERY MODE

09/20/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/017,798

Applicant(s)

KRAMER ET AL.

Examiner

Victor S. Chang

Art Unit

1771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-22, 24-27, 32-34 and 37-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-22, 24-27, 32-34 and 37-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Introduction

1. Applicants' amendments and remarks filed on 9/11/2007 have been entered. Claim 32 has been amended. Claims 19-22, 24-27, 32-34 and 37-42 are active.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. In response to the amendments, the grounds of rejection have been updated as set forth below.

Claim Rejections - 35 USC § 112

4. Claims 33, 34 and 42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

More particularly, the examiner repeats (see Advisory mailed 7/12/2005 and Office action mailed 8/31/2005) that phrases such as "repeated throughout at least most of said article", "repeated regularly throughout a substantial portion of said article", and "repeated substantially throughout the entire article" in claims 33, 34 and 42 are new matter. While the relied upon hand drawn illustration Fig. 2 of present application shows a desired localized structural feature which repeats twice in the drawing, nowhere in the specification shows such a feature is repeated

regularly throughout the article. In fact, the actual micrographs Figs. 3 and 4 of the present application are incommensurate with such a localized structural feature as being representative substantially throughout the article. It is noted that applicants have deleted similar limitation from independent claims in prior response filed 10/27/2005, then improperly reintroduced them in dependent claims.

5. Claims 19, 23-25 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

For claim 19, the recitation "... a first plurality of fibrils interconnecting said first node with a said second node, said first plurality of fibrils defining a first group of pores therebetween, said **first group of pores** falling substantially with in a **first size range** ..." (emphasis added) is vague and indefinite, because these terms are not defined in the specification, nor in relied upon Fig. 2, and it is unclear what is the scope of the term "first size range" is referring to: is it an *area range* which contains the first plurality of fibrils which defines a first group of pores? or is it the *pore size range* of the first group of pores? For the present Office action, in view of the similar limitation found in the dependent claims 24 and 25, the term "first size range" is interpreted as "pore size range of the first group of pores". Similarly, the term "second size range" is interpreted as "pore size range of the second group of pores". Clarifying claim language, similar to claims 24 and 25, is requested.

Rejections Based on Prior Art

6. Claims 19-22, 24-27, 32-34 and 37-42 are rejected under 35 U.S.C. 102(a) as being anticipated by Edwin et al. [US 6039755].

Edwin's invention relates to a tubular expanded polytetrafluoroethylene (ePTFE) microporous graft. The graft has a microstructure of nodes interconnected by fibrils. The nodes are elongated under radial expansion, and are substantially perpendicular to the longitudinal axis of the tubular ePTFE. The fibrils are oriented parallel to the longitudinal axis of the tubular ePTFE material [col. 2, lines 42-49; Figs. 1 and 2].

For claims 19-22, each of the micrographs in Figs. 18D, 21B or 21D shows the same local structural features as Fig. 2 of the present application, which has been stated by applicants as the basis of the recited structural features of claimed invention. Specifically, Edwin shows in the micrographs an expanded microporous ePTFE membrane having local regions in which there is a plurality of elongated and generally parallel large nodes, and small intermediate node between the large nodes. The large and small intermediate nodes are interconnected with a plurality of fibrils, which define different pore sizes in regions between the large/large nodes and large/small intermediate nodes. Edwin anticipates the instant invention as claimed. Regarding the limitation that the article is created from a mixture of a first resin and a second resin having a different molecular weight than said first resin, and then expanding said mixture, since any polymeric material inherently comprises a distribution of molecular weights, i.e., a mixture of molecules over a range of different molecular weights, Edwin's ePTFE anticipates the mixture of different weights as claimed.

For claims 24-27, Edwin shows in Fig. 18D that the lengths of fibrils for small pores in the range of 2-15 mm, and lengths of fibrils for large pores in the range of 20-50 mm.

For claims 32-34, Edwin's Figs. 18D, 21B or 21D read on the local structural features of instantly claimed invention as set forth above. The terms "first material" and "second material" in independent claim 32 are both read upon by Edwin's PTFE, because the term "material" lacks any limitation on composition and/or molecular structure. Even if different molecular weights are considered, since Edwin's polymeric PTFE material is inherently distributed over a range molecular weights, Edwin still anticipates the terms "first material" and "second material" as claimed. Regarding the limitation that the local structural features are repeated regularly and consistently throughout a substantial portion of the membrane, since applicants generally rely upon Fig. 2 for the local structural features between the nodes and fibrils [see reply filed 3/3/2005, page 3, and reply filed 10/27/2005, page 7], and Figs. 3 and 4 of present application provide an overall structural features of the mosaic pattern, the term "regularly and consistently throughout a substantial portion" is interpreted as the overall mosaic pattern shown in Figs. 3 and 4 (i.e., the intermediate node is present in substantial pairs of large nodes, but not between every pair of large nodes), and is clearly read upon by the same overall mosaic pattern shown in Edwin's Figs. 18C, 21A or 21C (Figs. 18D, 21B or 21D are magnified local regions in Figs. 18C, 21A or 21C). Finally, regarding the use limitation for blood contact application, since statements of intended use do not serve to distinguish structure over the prior art, it has not been given any patentable weight. See *In re Pearson*, 494 F.2d 1399, 1403, 181 USPQ 641, 644 (CCPA 1974).

For claims 37-42, since they claim the same scope of limitations of claims 19-22, 24-27 and 32-34, they are also rejected as set forth above.

Response to Amendment

7. Applicants agree [Remarks page 6] that the term “size range” in claim 19 refers to the size range of the pores, but argue that amending the wording of claim 19 would disrupt the plain meaning intended. However, since the term “size range” is not defined in the original specification, and could be interpreted either as an “area size range” of the fibers, or a “pore size range”, and renders the scope of invention vague, indefinite and confusing. The examiner maintains that clarifying claim language is required in the next reply. It is unseen how clarifying language, similar to claims 24 and 25, would have disrupted the intended scope of invention.

Applicants argue [pages 7-10] that the instant invention claims an intermediate node connected to the first and second nodes by relatively short fibrils (as illustrated in Fig. 2 of the present invention), therefore the internodal arrangement of the claimed invention is different than the Edwin arrangement in general. However, while Edwin discloses additional embodiments not relied upon, the relied upon disclosures by Edwin read on the instant invention as claimed. Since each of the micrographs in Figs. 18D, 21B or 21D shows the same localized structural features as Fig. 2 of the present application, applicants’ arguments directed to Edwin’s additional embodiments not relied upon are misplaced and unpersuasive.

Applicants argue [pages 10-11] that the internodal distance arrangement of the present invention is recited as being repeated at least twice - once between the first node and an adjacent third node, and again between the second node and an adjacent fourth node. The repeated pattern

in Edwin's illustrations and micrographs shows a repeated pattern of elongated nodes and elongated fibrils without any intermediate nodes. However, applicants are reminded that Fig. 2 is merely a hand drawn illustration of a localized feature, which is not a representation of the general internodal arrangement as shown by applicants' own Figs. 3 and 4. While it is proper to claim a localized feature in an open ended "comprising" clause, it does not exclude any other localized features, including applicants' own varieties of other localized features found in Figs. 3 and 4. The examiner asserts that such a localized feature has been identified in Edwin's microporous graft, as set forth above. Further, applicants appear to be arguing against their own illustration and micrographs.

Applicants argue [page 11] that the examiner has not made a record as to why the recited pore ranges are met. However, the examiner has pointed out that Edwin shows in Fig. 18D lengths of fibrils for small pores in the range of 2-15 mm, and lengths of fibrils for large pores in the range of 20-50 mm.

Applicants argue [page 12] that claim 32 requires a composition of two different materials. However, the claim merely recites "first material" and "second material", there is no requirement that they are different in composition, nor in molecular weights.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor S. Chang whose telephone number is 571-272-1474. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel H. Morris can be reached on 571-272-1478. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

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like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Victor S Chang/
Primary Examiner, Art Unit 1771

9/18/2007